REMARKS

Restriction

Applicant just recently noted that the previous restriction requirement failed to associate Claim 13 with any specific group. Applicant carried this oversight in failing also to point this in its prior response, but now respectfully requests that claims 13, which is dependent of claim 12 and is directed to a process of making the fleece, be examined and reconsidered along with the present claims under examination.

Objection to Specification:

The specification is objected to for the use of the trademark name FocalSeal-S in Example 11 as the identifier for the materials used in that experiment. The generic description for FocalSeal-S macromer is provided earlier in the text before the Example section and is now imported into example 11 to comply with the Examiner's request. Support is found on page 23, lines 5-14. Applicant believes that this amendment does not constitute new matter.

Support for claims amendment:

Claim 1 and 4 are amended to recite "composition". Support for this amendment may be found throughout the specification.

Claim 1 is amended to recite the crosslinking step to occur in the frozen or dried state. Support for this amendment can be found in the specification at least on page 13, lines 1-5, on page 14, lines 19-20, and page 15, lines 10-14.

Claim rejection under 35 USC §112, second paragraph:

1. Claim 3 is rejected for being indefinite in its recitation of "vacuum-drying the solution". Applicant has amended the claims to refer to "composition" instead of "solution". Applicant believes this amendment overcome the rejection and kindly request that it be withdrawn.

2. Claim 4 is rejected as being vague and unclear in the recitation of "biologically active agent". Applicant respectfully disagrees. The term "biologically active agent" is well understood in the art. Also, the specification provides guidance as to what is a biologically active agent. At page 18, starting at line 1 for example the term is described as broad as "any of a wide variety of substances which can influence the physiology or structure of a living

organism". The description also goes on to further refine therapeutic uses of the term (see page 18, lines 1-9).

The examiner seems to object to the term because the term "is relative to how any given agent is used or viewed by the artisan". In short the examiner rightly perceive that such a term encompass various types of use, but seems to misguidedly require that applicant limit the scope of these agents to certain uses. In support of this argument, the examiner presents an exemplary sample containing a material which could be a neurotoxin, as if to imply that patentability under §112, second paragraph could only be found for combination not having nefarious effects.

Is the examiner questioning the utility of these combinations? If so, Applicants respectfully requests that appropriate rejection be so articulated so that it may appropriately reply under the utility requirement[1].

But, patentability assessment under §112, second paragraph does not require such a test. All that is required under §112, second paragraph is that the scope of the claims be clear so the public is informed of the boundaries of what constitutes infringement of the patent and has a clear measure of what applicant regards as the invention. See MPEP §2173. Because a skilled artisan would easily be able to determine if an agent satisfies the present limitation, it is irrelevant that such a definition captures a broad range of materials, and such does not render the claims vague and unclear. See MPEP§2173.04; *In re Miller*, 441 F2d. 689, 169 USPQ 597 (CCPA 1971) (Breadth of a claim is not to be equated with indefiniteness). Accordingly, applicant believes that the term "biological active agent" is clear and definite and respectfully requests that this rejection be withdrawn.

3. Claims 9, 10 and 15 are rejected for being indefinite on the basis that the claims are allegedly "incomplete because how a sample is 'shredded' is not clearly set forth, in particular for fleece particles that are small." Applicant respectfully disagrees. Claim 9 and 10 recite the step of "shredding the crosslink macromer". The crosslinking of the macromer composition forms a cohesive mass. The step of shredding that cohesive mass is to break it down into masses of smaller size such as particulate sizes. Example 11 at pages 31-32 describe an exemplary

[1] But, applicant would remark that neurotoxins compositions have utility, even therapeutic beneficial uses approved by the FDA (e.g. botulinum toxin in the treatment of cervical dystonia). Even pesticides have nefarious biological effects to the pest, but utility to humans.

apparatus by which shredding of the fleece may be conducted; same at Example 16, page 36 describing manual shredding and mechanically assisted shredding. Thus applicant believes that the step of shredding is clear and definite and respectfully requests that the rejection be withdrawn.

4. Claim 12 is rejected as being indefinite in the recitation of "supporting material". The applicant respectfully disagrees. Here again, the examiner seems to have equated breadth with indefiniteness. In his support of this rejection, the examiner states "what would be considered a supporting material and how it 'is incorporated' would be subject to different interpretation of the term 'supporting'". The mere fact that a term encompasses several embodiments does not render the claim term indefinite; it is just evidence of breadth. Applicant submits that this term is well understood within material sciences. Therefore, applicant believes that this term is clear and definite and respectfully requests that this rejection be withdrawn.

Claim Rejections under 35 USC §102(b)

1. Claims 1-12, 15 and 16 are rejected under 35 USC §102(b) as allegedly being anticipated by DeLuca et al. (US Patent 4,741,872). Applicant has amended the claims to recite that the step of crosslinking is performed when the composition is in the frozen or dried state.

DeLucas does not teach processes in which the crosslinking occurs in the solid state such as the frozen or dried state as presently claimed here. DeLucas only teaches a process in which the crosslinking occurs in the liquid state.

Applicant thus submits that the claimed process is novel over the cited art and respectfully request that the rejection be withdrawn.

2. Claims 1-12, 15, and 16 are rejected under 35 USC §102(b) as allegedly being anticipated by Yannas et al. (US Patent 4,955,893). Applicant has amended the claims to recite that the step of crosslinking is performed when the composition is in the frozen or dried state.

Yannas does not teach processes in which the crosslinking occurs in the solid state such as the frozen or dried state as presently claimed here. Yannas only teaches a process for freeze-drying. The polymer is provided either in the uncrosslinked or as already crosslinked.

Applicant thus submits that the claimed process is novel over the cited art and respectfully request that the rejection be withdrawn.

3. Claims 1-12, 15, and 16 are rejected under 35 USC §102(b) as allegedly being anticipated by "Yannas et al. (US Patent 4,741,872)" (sic). Applicants requests clarification for this rejection as the identified patent number corresponds to the DeLucas, not the Yannas, Patent. In any case, Applicant perceives this rejection as being redundant to the previous two rejections and thus respectfully submits that the present claims are novel over both pieces of prior art. Accordingly Applicant respectfully request that this rejection be withdrawn.

FIRST NAMED INVENTOR:	SERIAL NO:	FILING DATE	ART UNIT:	CONF. NO.
Hildegard M. Kramer	10/075,355	Feb. 14, 2002	1633	8887
TITLE:			EXAMINER:	
Biocompatible Fleece For Hemostasis and Tissue Engineering			Joseph T. Woitach	

PETITION FOR EXTENSION OF TIME

Applicant hereby petitions the Commissioner of Patents for a **three-month** extension of time to extend the period for responding to the Office Action to March 22, 2005.

AUTHORIZATION FOR PAYMENT OF FEES

Applicant authorizes the payment of fees due with this submission as designated below or of any additional fee to Deposit Account **07-1074**.

Description	37 CFR §	Fee Code	Fee
3-month extension	1.17(a)(3)	1253/2253	$1020.00
		Total	**$1020.00**

Respectfully submitted,

Date: March 22, 2005

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